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107.

synthesizing enzyme is a plant gene coding for trehalose phosphate synthase.

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#### REMARKS

The Official Action of July 12, 2002 has been carefully considered and reconsideration of the application as amended is respectfully requested.

Claim 35 has been amended to provide antecedent basis for the recitations in claim 48 and in newly added claim 66. The dependency of claim 61 has been changed to correct an inadvertent error and thereby to remove the basis for the Examiner's rejection of claims 61 and 62 in the last paragraph on page 2 of the Official Action. All claims as amended are believed to be sufficiently definite to satisfy the dictates of 35 USC 112, second paragraph.

New claims 66-69 have been added more completely to define the subject matter which Applicants regard as their invention. The recitations in the new claims draw clear support from the specification as filed at, for example, page 9, line 13 to page 10, line 4, and the Examples, as discussed further below.

The claims stand rejected under 35 USC 112, first paragraph, because the specification is allegedly not enabling for (a) non-validamycin chemical trehalase inhibitors, (b) plants which naturally produce trehalose or (c) plants transformed with transgenes other than bacterial or fungal genes encoding trehalose phosphate synthase (TPS). Applicants respectfully traverse this rejection.

With respect to the reason for rejection (a), Applicants submit herewith a Declaration under 37 CFR 1.132 which shows that (i) chemical trehalase inhibitors other than validamycin are able to inhibit endogenous trehalase and thereby to

enhance accumulation of trehalose in plants, and (ii) such trehalase inhibitors can be routinely tested using the methods exemplified in the present specification as filed. As discussed in MPEP Section 2164.01, the test for enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. The Declaration submitted herewith shows that the experimental techniques described in the specification can be used routinely to test chemical trehalase inhibitors other than the exemplified validamycin. Indeed, there is no reason why any prospective chemical trehalase inhibitor could not be routinely tested using the methods taught in the specification. Under these circumstances, it is respectfully submitted that the specification as filed is enabling for chemical trehalase inhibitors as broadly claimed.

With respect to the reasons for rejections (a) and (b), Applicants respectfully call the Examiner's attention to the fact that the claims are written in Jepson format so as to separate those elements or steps of the claimed combination that are conventional or known from those elements or steps that constitute that portion of the claimed combination which Applicants consider as the new or improved portion (see 37 CFR 1.75(e)). The application need not teach, and preferably omits, those elements of steps which are known. See, e.g., MPEP Section 2164.01 and cases cited therein. The known elements include plants which produce trehalose either naturally or by transformation thereof (see preamble of claims 35 and 63 and "State of the Art" section on page 1 of the specification).

The invention as claimed takes as a starting point (known) plants that naturally synthesize trehalose or that have been genetically altered to synthesize trehalose. By placing these elements in the preamble of claims 35 and 63, Applicants acknowledge

that these elements are known and that they are not part of the subject matter which Applicants regard as their invention. Accordingly, it is respectfully believed to be irrelevant to the invention as claimed whether the recited plants naturally produce trehalose or, if the plants have been genetically altered with a gene encoding a trehalose synthesizing enzyme, what the source of the gene is.

In this latter connection, Applicants respectfully call the Examiner's attention to the fact that, in addition to bacterial and fungal genes encoding trehalose synthesizing enzymes, the specification also describes and exemplifies applicable plant genes that can be used in the claimed process. So, for example, Example 9 on pages 25-26 of the specification exemplifies the isolation of a bipartite TPS/TPP gene from *Helianthus annuus*. Applicants' specification also lays out how to isolate other bipartite TPS/TPP genes, in particular that of tobacco (see Example 10 on pages 26-27 of the specification).

In the rejection, the Examiner has specifically referred to (i) the alleged unpredictability that a multitude of plants would naturally produce trehalose, and (ii) the alleged toxicity of trehalose for plants, which toxicity would allegedly be exacerbated by the inhibition of trehalase. Applicants respectfully submit that these issues are irrelevant to the invention as claimed. The claims read only on plants that **do** naturally produce trehalose or plants that have been genetically altered to produce trehalose. The claims do not read on plants that do not naturally produce trehalose and that have not been genetically altered to produce the same. *A fortiori* the claims do not read on plants that, whether due to alleged trehalose toxicity or otherwise, do not produce trehalose. Moreover, the determination of which plants satisfy the

claimed requirements (i.e., those that produce trehalose) would not require undue experimentation given that means for testing the plants for trehalose production were well known to those of skill in the art at the time the application was filed and is also described in the specification (see, e.g., specification at paragraph bridging pages 18-19).

In view of the above, it is respectfully submitted that the specification as filed is enabling for the invention as broadly claimed.

The Examiner has also rejected the claims under 35 USC 112, first paragraph, for alleged violation of the written description requirement. Applicants respectfully traverse this rejection.

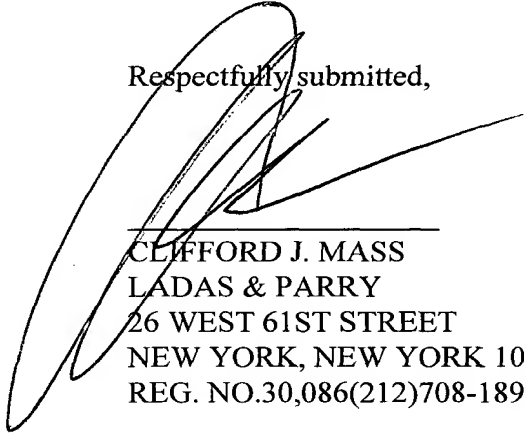
The rationale for the rejection is that the specification as filed allegedly does not show that Applicants had possession as of the application filing date of TPS genes other than TPS genes from bacterial or fungal sources, and that the specification therefore does not show possession of a broad genus of TPS genes. Applicants first note that, as discussed above, the specification, in addition to describing bacterial and fungal genes, also describes plant TPS genes. Accordingly, the specification **does** describe a representative number of species within the claimed genus.

In any event, Applicants respectfully call the Examiner's attention to the Jepson format of the claim and note that Applicants are not claiming a genus of TPS genes. By definition, the subject Jepson claims are drawn to an improvement in a process for the production of trehalose in plants, wherein the gene that is used for the production of trehalose in the plants is not only not part of the claimed improvement, it is acknowledged as being conventional or known in the art (see 37 CFR 1.75(e)). In

any event, the claims are not drawn to a genus of genes *per se* and Applicants need not show possession of any specific genes or genus of genes in order to describe the claimed **process**. In this respect, the case law cited by the Examiner is respectfully believed to be inapposite, and the specification as filed is believed adequately to describe the claimed invention under the provisions of 35 USC 112, first paragraph.

In view of the above, it is respectfully submitted that the rejections and objections of record should be withdrawn. The application is respectfully believed to be in allowable form and an early notice of allowance is earnestly solicited and is believed to be fully warranted.

Respectfully submitted,



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Please amend the following claims.

Claim 35 (twice amended) In a process for producing trehalose in plant cells, plants or parts thereof, wherein the plants naturally synthesize trehalose or are genetically altered to synthesize trehalose so as to contain a gene coding for a trehalose synthesizing enzyme, said plants naturally comprising an endogenous trehalase activity, the improvement comprising:

(a) inhibiting the endogenous trehalase activity in the plants or parts thereof and cultivating the plants to allow an accumulation of trehalose in the plants or parts thereof; and

(b) screening for a plant or a plant part having a level of trehalose that is increased as a result of said inhibiting.

Claim 61 (amended) A process according to claim 43 [44] wherein the plant or the part thereof is from a *Solanaceae* species.